

X: INTERNATIONAL RESEARCH

AREA OF EMPHASIS:

International Research

SCIENTIFIC ISSUES

Now in its third decade, the AIDS epidemic continues its relentless spread across the globe. The devastating effect of AIDS is broad, wiping out development gains, decreasing life expectancy, increasing child mortality, orphaning millions, setting back the situation of women and children, and threatening to undermine national security in highly affected societies. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), at the end of 2003:

- An estimated 40 million people worldwide were living with HIV/AIDS;
- Approximately 2.5 million were children under the age of 15 years;
- About half of the infected adults were women;
- An estimated 5 million people (adults and children) acquired the HIV virus in 2003; and
- The global HIV/AIDS epidemic killed more than 3 million people in 2003.

UNAIDS notes in its December 2003 report *AIDS Epidemic Update* that the sub-Saharan Africa region remains the hardest hit by the epidemic. At the end of 2003, there were an estimated 26.6 million people living with HIV/AIDS in sub-Saharan Africa, and approximately 3.2 million new infections occurred during 2003 alone. Epidemics have also long been

established in Latin America and the Caribbean, where approximately 2 million people were living with HIV/AIDS as of the end of 2003. After sub-Saharan Africa, the Caribbean is the most affected region in the world, with an overall prevalence rate of approximately 2.5 percent among adults. Haiti has the highest adult prevalence rate (5–6 percent), followed by the Bahamas (3.5 percent). Meanwhile, the epidemic in Central America continues to worsen, particularly among the socially marginalized sections of the population.

In other regions of the world, HIV/AIDS epidemics are rapidly escalating. In Asia and the Pacific region, more than 1 million people acquired HIV in 2003, bringing the number of infected persons to an estimated 7.4 million. There are increasing signs that serious HIV outbreaks threaten in several countries in the region. Injecting drug use and sex work are so pervasive in some areas that even countries with currently low infection levels could see epidemics suddenly surge. The Eastern European and Central Asian region has the fastest growing HIV/AIDS epidemic in the world, with approximately 1.5 million people living with HIV/AIDS. The Russian Federation is experiencing an especially steep rise in HIV infection, with transmission attributed to injecting drug use in the majority of reported cases.

Research is an essential component of a comprehensive approach to address the global AIDS pandemic. Since the early days of the epidemic, the NIH has been supporting an increasing research effort in countries affected by HIV and AIDS. Beginning in 1984 with a research project in Haiti and the establishment of *Projet SIDA* in 1985 in what was then Zaire, the NIH has maintained a strong international research portfolio. Development of a research infrastructure, including training of scientists and health care providers, is an essential adjunct to these research programs. The NIH has expanded its research effort on HIV/AIDS to encompass an increasing number of countries around the world, particularly in resource-limited settings, and collaborations between scientists in the United States and in developing countries have increased in number and scope. Results of this research benefit not only the people in countries where the research is conducted, but, indirectly, people affected by HIV/AIDS worldwide.

The NIH international research portfolio continues to evolve. In 2000, the Office of AIDS Research (OAR) established a new initiative and plan for global research on HIV/AIDS, which has been updated yearly. In the planning and implementation of its international AIDS research portfolio, the NIH collaborates with in-country scientists, host country governments, UNAIDS, the World Health Organization (WHO), foundations, and nongovernmental organizations (NGOs).

There is an urgent need in resource-poor countries for effective, culturally appropriate, and sustainable interventions to prevent transmission of HIV and to treat HIV and associated complications in both adults and children. There is also a need to integrate prevention and care interventions to ensure that an increasing proportion of the population has access to an integrated set of health services. NIH-sponsored research can identify and test such interventions, thus providing the basis for their implementation. As part of this overall effort, NIH-sponsored research will also develop better methods, both quantitative and qualitative, to evaluate the effects of prevention and treatment programs.

Information gained through NIH-sponsored research must be translated into public health measures that will enhance patient management, improve prevention programs, and inform policy decisions in resource-poor settings around the world. To facilitate this process, operational research is of critical importance to assess, through advanced analytical techniques, different ways to achieve the desired outcomes in a country's specific context.

There is great diversity among international settings with respect to prevention and treatment research needs, and an overriding principle guiding the conduct of NIH-supported international AIDS research is that the research effort must be relevant to the cultural, social, and economic context of the country where the research is conducted. Two steps to accomplish this are involving the local community throughout the development of the research effort and ensuring a leadership role for in-country scientists.

PRIORITY FOR FUTURE RESEARCH:

- **Develop in-country HIV/AIDS research and training infrastructure for the conduct of integrated prevention and treatment or care intervention research, integrating new activities into existing health care and prevention services.**

Various sections of the *NIH Plan for HIV-Related Research* describe research efforts to develop HIV vaccines; chemical and physical barrier methods, such as microbicides, to prevent sexual transmission; behavioral strategies targeted to the individual, family, and community to alter risk behaviors associated with sexual activity and drug and alcohol use; drug and nondrug strategies to prevent mother-to-child transmission (MTCT); therapeutics for HIV-related coinfections and other conditions; and antiretroviral therapy (ART) regimens and strategies for widespread use in resource-poor settings. But before prevention and treatment interventions can be implemented, their safety and efficacy must be

demonstrated in such settings by clinical trials and other intervention research. However, in many resource-poor countries, adequate infrastructure may not exist to conduct such trials and must be developed.

Several principles guide the development of infrastructure. One is that many of the clinical and infrastructure needs for clinical trials are best developed through the conduct of research in these settings, since clinical and population-based research are effective means to prepare for eventual clinical trials. A second principle is that infrastructure development is enhanced when the research effort is integrated with ongoing health care and prevention services and when prevention and care services themselves are integrated, enabling prevention messages to be delivered in the care setting.

Specific infrastructure needs are many. In order to move quickly with clinical trials of promising products and strategies, research sites must be strengthened through establishment of stable, targeted cohorts; development of recruitment and retention strategies; and enhancement of laboratory, clinical, and data management capabilities. To ensure the leadership role of in-country researchers, it is critical to increase the number of scientists, clinicians, and health care workers of all levels and disciplines who are trained in basic, clinical, and behavioral research; data management; program management and administration; and ethical considerations. To develop an adequate cadre of researchers in resource-limited countries, it is also essential to develop strategies to retain researchers in-country and enhance the careers of trained personnel. Alongside the need to train and retain researchers is the need to develop strong and effective research collaborations involving both U.S. and foreign colleagues. Finally, high-quality research in resource-limited settings can be carried out only if adequate clinical and laboratory technologies are transferred to such settings. Critical to the effort to strengthen infrastructure is the need to devise innovative funding mechanisms and approaches, such as the evolving policy on provision of indirect costs to foreign institutions.

PRIORITY FOR FUTURE RESEARCH:

- **Define the spectrum of HIV-related disease and its response to treatment as it applies to diverse geographic settings, and develop integrated prevention and treatment interventions to limit the impact of HIV-related disease.**

Since the beginning of the AIDS epidemic, research has been conducted in the industrialized world to characterize the opportunistic infections (OIs) that affect individuals whose immune systems are weakened by HIV.

Methods for diagnosis, prevention, and treatment of OIs have been developed. The extensive use of potent ART (or HAART, highly active antiretroviral therapy) in the industrialized world has resulted in a dramatic decrease in many of these infections and their related morbidity. In the developing world, however, OIs associated with HIV continue to result in high morbidity and mortality. Much remains to be elucidated about the extent of endemic coinfections, cancers, neurologic manifestations, and other conditions associated with HIV infection in these settings. It is necessary to develop and assess different and complementary modalities to prevent and treat them, particularly since antiretroviral drugs (ARVs) are only beginning to be used in these settings. The needs of both adults and children must be addressed in these efforts. As a foundation for the development of such interventions, it is essential to characterize the nature, prevalence, risk factors, and disease course of endemic coinfections, as well as other HIV-related conditions found in diverse geographic settings. An integral component of this effort is the development of diagnostic methods to detect these illnesses.

Sexually transmitted infections (STIs) have been recognized as key cofactors that sustain the AIDS epidemic, and many aspects of the relationship between HIV infection and other STIs have been investigated in developing country settings. However, other aspects of this interaction are still elusive, e.g., the relative contribution of different STIs to HIV transmission and which control strategies can best take their relative importance into account; the possibility of frequent cotransmission of STIs and HIV; and the potential role of sexually transmitted disease (STD) clinics as sites to detect acute HIV infection, using new instruments for detection.

Important new information about the global extent and nature of concomitant infection with hepatitis C virus (HCV) is beginning to emerge, and research is needed to further characterize HIV/HCV coinfection. The HIV-related global epidemic of tuberculosis (TB) is well documented, with approximately a third of the world's population of HIV-infected individuals coinfecting with *Mycobacterium tuberculosis*. As TB is now the leading cause of death among HIV-infected individuals worldwide, research to develop approaches to prophylaxis and treatment of TB remains a priority.

Further, little is known about other infections and resulting pathologic conditions. Some are closely related to specific environments. For example, fungal infections might prevail in one setting and bacterial infections in another. Diseases not found in industrialized nations may be important in more resource-diverse regions (e.g., a fungal infection due to *Penicillium marneffei* is an important coinfection in HIV-infected individuals in some

areas of Southeast Asia, where the agent is endemic). In addition, it will be critical to examine the impact of new interventions on diseases such as malaria, not previously thought to be related to HIV but a major cause of morbidity and mortality in developing countries.

Research on treatment strategies and specific regimens will be necessary to understand and curtail possible undesired effects of therapies. In the industrialized world, extended survival in individuals receiving ART has been associated with the development of a spectrum of new systemic conditions, e.g., metabolic and cardiovascular disorders. As the use of ART increases in the developing world, it will be necessary to characterize new pathologic conditions that may be influenced by factors such as diet, the presence of endemic diseases, and the use of drugs to treat them.

PRIORITY FOR FUTURE RESEARCH:

- **Conduct studies (experimental and observational) to identify the appropriate modalities of introduction and long-term use of ART in resource-limited settings.**

The use of ART has extended the length and improved the quality of life for many HIV-infected people in industrialized countries. These therapies have not yet been widely utilized in resource-poor nations, due to factors such as cost and the need for an adequate health care infrastructure to administer and monitor these therapeutic regimens. However, momentum has grown to provide ART in these regions. Treatment programs have been launched by international organizations (e.g., WHO, the Global Fund), U.S. organizations (e.g., the President's Emergency Plan for AIDS Relief [PEPFAR]), and a large number of NGOs. It is, therefore, critical to move rapidly to investigate the safety and efficacy of various ART regimens for both adults and children in diverse resource-poor settings. For example, differences in diet, nutritional status, or the use of medications for endemic diseases may alter the toxicity or the efficacy of ARVs as compared with industrialized areas. Practices in industrialized countries may not be directly applicable, due to many factors such as existing health care infrastructure, social structure, and the presence of other endemic diseases, as well as factors related to the patients themselves and their families. Thus, many questions about how to treat and how to monitor patients infected with HIV must be adapted to variable developing country settings. Research is needed to address adherence to medication regimens and ways to monitor and improve it. Any ART program will be associated with variable levels of resistance to ARV, an issue that will require different types of research studies, ranging from basic science laboratory investigations to studies of ART effectiveness and outcome research, in

order to document its mechanistic underpinnings, its epidemiologic features, and its possible consequences at the individual and population level. Studies will also be warranted regarding the potential increase of high-risk behavior that, as a result of a false sense of security, may occur when ART becomes more widely available.

In order to move rapidly in this field, the laboratory and human resource infrastructure already established in the developing world needs to be further developed for the specific requirements of treatment research, including the training of in-country scientists, clinicians, and other health care workers. Operational research questions must be addressed about the implementation of current technologies for viral load and CD4+ cell measurements and the development of lower cost methods and alternatives for these tests. The need to move rapidly will require the use of creative and flexible funding mechanisms. Finally, a dialogue with the pharmaceutical industry should be continued concerning the provision of drugs for the research effort and for treatment regimens once they have been demonstrated safe and efficacious.

PRIORITY FOR FUTURE RESEARCH:

- **Support studies to identify effective, appropriate, and sustainable interventions to curtail HIV transmission. Such interventions should encompass the prevention of all transmission modalities (e.g., heterosexual, mother-to-child, transmission related to drug and alcohol use) and their mutual interaction. Intervention modalities to decrease HIV transmission should integrate evidence acquired from biomedical, behavioral, and other research areas and should identify and target all at-risk populations.**

The NIH is pursuing international research in all scientific areas that address HIV transmission. From a global perspective, the major modes of acquiring HIV infection are unprotected heterosexual intercourse and injecting drug use, with the vast majority of infections occurring through sexual transmission. Appropriate and acceptable biomedical and behavioral interventions to curb this transmission in very diverse settings are urgently needed, interventions that must address specific populations at risk, such as women and adolescents.

Behavioral and social interventions are needed at all levels: individual, family, social network, community, and society. These interventions must be developed for seropositive as well as seronegative individuals. Women are particularly vulnerable, comprising about 50 percent of adults worldwide who became infected during 2003. It is critical to develop microbicides

and other prevention methods that can be controlled by women. It also is important to address social factors that contribute to vulnerability to HIV transmission and that serve as possible points of intervention. These include stigma and discrimination, and gender inequality. Research also is needed to devise strategies to decrease HIV transmission in health care settings.

Two prevention intervention needs merit special attention: prevention of MTCT and transmission related to drug and alcohol use. Since 1994, industrialized nations have experienced a dramatic decrease in MTCT through the use of a complex regimen of ARVs, coupled with access to voluntary counseling and testing, use of cesarean section, and avoidance of breastfeeding. However, preventing MTCT is a significant challenge in resource-poor settings of the world, where these regimens are too expensive and complex to implement; operative delivery may not be safe and could threaten the health of the mother; and HIV-infected women continue to breastfeed due to stigma and discrimination toward nonbreastfeeding women and the lack of safe, affordable, and acceptable alternatives to breastfeeding. While clinical trials have demonstrated that a variety of short, simple, effective, and inexpensive ARV regimens also can reduce MTCT by up to 50 percent, the results have been slow to be implemented, and postnatal transmission through breastfeeding remains a significant problem. New interventions will need to be developed to further reduce MTCT, and operations research will need to be conducted to facilitate implementation of effective prevention strategies and regimens.

Injecting drug use is a growing factor in the AIDS epidemic. As a social phenomenon, injecting drug use itself is reported to be growing in all regions of the world, including Africa. Thus, the potential exists for drug-related epidemics to arise in new places and for escalation of established epidemics. In some countries in Asia and Central and Eastern Europe, injecting drug use is now the major route of HIV transmission. Recent rapid increases in HIV infections in China, Indonesia, and Viet Nam show how an epidemic can erupt suddenly whenever significant levels of injecting drug use occurs.

Injecting drug users (IDUs) who share needles and other contaminated equipment are at high risk of acquiring or transmitting HIV as well as other blood-borne pathogens, such as HCV. However, the use of noninjecting drugs, including alcohol, also is associated with increased risk, particularly through associated sexual behavior. Of great concern is the use of alcohol and other drugs among young people. Alcohol is related to behavioral disinhibition, and as the most widely used drug in the world, may be associated with the spread of HIV in a variety of social contexts. In many parts of the world, drug use and sexual transmission of disease

are inextricably linked, and drug users are more likely to be involved in the sex industry, greatly enhancing their risk of infection and the chances of HIV's spreading even wider in the community. IDUs are particularly vulnerable to HIV and AIDS because they are often poor and marginalized. To prevent transmission related to drug and alcohol use, culturally relevant interventions are needed. To ensure that newly developed interventions are culturally appropriate, it is critical to conduct research that investigates the social context of drug and alcohol use and to involve the community at all levels of the research.

PRIORITY FOR FUTURE RESEARCH:

- **Study and address barriers to the conduct of international research, including access to health and research facilities for at-risk populations, research regulatory requirements, consistent application of bioethics principles, institutional factors (e.g., availability of expert peer review groups and program personnel), and others.**

The development of research infrastructure through training of researchers, strengthening of laboratory and clinical capacity, and development of research collaborations will help to address many of the existing challenges to the conduct of research in resource-limited settings. However, additional challenges remain that need to be addressed.

Ethical considerations must be paramount in the development of international collaborations and NIH support of research activities in other countries. It is universally accepted that researchers should adhere to standard ethical principles in the design and conduct of research. Essential to the protection of human subjects participating in research, these principles are outlined in several documents and include respect for persons, beneficence, and justice. However, the vastly different economic and cultural contexts in which research is conducted in international settings create many challenges for researchers and funding agencies in the application of these principles. For example, obtaining voluntary informed consent from each study participant may be complicated in some settings by social customs requiring the involvement of others in the community in this process, such as family members or community leaders; lengthy and complex informed consent forms used in the United States may be problematic to use in these settings. Differences in laws, regulations, and public policy, as well as organizational structures, mean that careful consideration must be given to how ethical standards of both the United States and the country where research is conducted can be met. To this

end, a more consistent dialogue is needed among U.S. and foreign investigators, foreign institutional review boards (IRBs), staff of the Office for Human Research Protections, NIH program managers, and ethicists.

Similarly, compliance with regulatory requirements in resource-poor settings often poses serious challenges that may result in long delays and added costs to key research studies. In addition, just as there is a great difference between clinical hospital sites in the United States and developing countries, there also is a great difference between developing country hospitals and field sites in their capacity to implement regulatory requirements. In this regard, it is important to indicate early in the research planning process whether or not the research is intended to support product approval by the U.S. Food and Drug Administration (FDA). Dialogue similar to that for ethical considerations is needed to develop common understanding of regulatory requirements and should include U.S. and foreign investigators, staff of the FDA, NIH program managers, and industry representatives as appropriate.

Several issues related to ART and international research are currently being debated to facilitate HIV/AIDS research in resource-limited countries. These issues include the use of research funds to acquire drugs (or other products) for clinical trials; the provision of ART to study participants at the end of treatment trials; and referral to treatment programs for individuals shown to be seropositive during screening for entry into studies and for those who become infected with HIV during the course of a vaccine or other prevention trial. These issues have substantial ethical, financial, and organizational ramifications for NIH-supported research.

Additional institutional challenges include the need to link research programs with prevention, treatment, and care programs, integrating prevention and care where warranted; enhancing the ability of study sections and review groups to address proposals for international research; and developing the expertise of program staff to manage international research portfolios. In addressing all these institutional issues, coordination among funding agencies—within the United States and around the world—will be necessary. The establishment of a database that tracks ongoing efforts funded through a variety of mechanisms would be of great assistance in such coordination. In addition, a single, comprehensive source of information relevant to the conduct of research, such as application procedures, ethical and regulatory requirements, and other policy issues would be of great assistance to foreign investigators and their U.S. collaborators.

Finally, a number of interrelated issues act as barriers to international research by affecting access of individuals to clinical studies. These social and cultural issues include gender inequities, poor health-seeking behaviors, and stigma and discrimination. Since the earliest days of the epidemic, stigma and discrimination have been associated with AIDS. Much of this stigma and discrimination is related to the mode of HIV transmission, and its impact is evident at government, societal, family, and individual levels, as well as in the health care setting. Stigma and discrimination prevent individuals from participating in clinical studies, due to fear that a positive serostatus would become known to family and community members, fear that a positive serostatus might be presumed simply because of study participation, or fear of being thought to be a member of an at-risk group. Stigma and discrimination are compounded by gender inequities, and women have less access than men to clinical studies—and therefore to the benefits of participation. Both men and women may have poor health-seeking behaviors because of other economic or familial pressures, and many times it is those who need it most that do not access services. Thus, strategies are needed to combat stigma and discrimination, address gender inequities, and improve health-seeking behaviors, particularly of infected and at-risk populations in resource-poor settings.

SCIENTIFIC OBJECTIVES AND STRATEGIES

OBJECTIVE - A:

Build sustainable research capacity and scientific leadership in international settings, in collaboration with scientists from the country(ies) under study, that will: (1) provide an environment that promotes the development of equal partnerships between U.S. and foreign investigators; (2) facilitate the conduct of basic, clinical, sociocultural, and behavioral research and long-term cohort studies; (3) serve as loci for studies of prevention and treatment interventions, including studies of the safety, efficacy, and effectiveness of these interventions; (4) train investigators from country and regional programs; and (5) integrate with programs that provide services and study models of effective delivery of care, such as those that integrate prevention and care.

STRATEGIES:

Site Development

- Assess existing sites and, as needed, further develop sustainable, existing in-country sites, or establish new international research sites as rapidly as possible, addressing geographic regions and specific populations where HIV is and/or will be a major cause of morbidity and mortality.
- Enhance capacity for the conduct of basic and applied research, clinical trials, and studies of the clinical aspects of HIV and related conditions, with emphasis on good clinical practice (GCP) of the intensity and rigor needed for large-scale trials through:
 - ▶ conducting ongoing incidence assessments in a variety of risk segments of the population;
 - ▶ enhancing laboratory capacity with appropriate quality assurance and improvement;
 - ▶ developing affordable alternatives to viral load and CD4+ cell counts for monitoring treatment efficacy and toxicity;
 - ▶ developing clinical capabilities;
 - ▶ improving capacity for voluntary counseling and testing and partner notification;
 - ▶ enhancing data collection and analysis capabilities;

- ▶ funding the analysis of scientific and research-based international databases and developing common laboratory information management systems;
 - ▶ addressing problems in maintaining repositories of biological samples in developing countries, such as loss of electrical power;
 - ▶ developing strategies for recruitment and retention of participants into prevention, treatment, and care studies, including research on factors related to adherence, recruitment, and retention;
 - ▶ enhancing the ability to ensure protection for human subjects involved in research and the ethical conduct of research, including informed consent and issues specific to mothers and children (e.g., role of the father);
 - ▶ linking HIV testing and care to services for alcohol abuse, drug abuse, mental health, family planning, and primary care; and
 - ▶ enhancing mechanisms for information exchange among investigators, including enhanced communication and collaboration via the Internet and telephone capability.
- Build global capacity to support the integration of clinical, operational, and health services research.
 - Conduct studies of incidence and feasibility in order to identify sites suitable for the conduct of efficacy trials of HIV prevention, treatment, and care interventions.

Training

- Continue to support training, both in-country and in the United States, of clinicians (physicians and nonphysician professionals, e.g., nurses, midwives, etc.), public health professionals, and scientists from developing nations to enhance the conduct of research on HIV, AIDS, STDs, and other HIV-related coinfections and malignancies, including research training related to (1) clinical aspects, (2) treatment and care (e.g., clinical trials of therapeutic strategies for HIV and endemic coinfections), (3) development and testing of vaccine candidates, (4) impact of alcohol and other substance abuse/dependence on HIV transmission, (5) HIV-related reproductive health, (6) disease progression, (7) prevention of MTCT, and (8) other biomedical, social, and behavioral prevention research.

- Enhance training in translational and operational research, including implementation and evaluation of prevention intervention strategies, treatment and care approaches, and feasible, cost-effective surveillance systems.
- Provide training in data management and analysis for in-country research personnel.
- Develop in-country training partnerships, and support “south-to-south” training to enable investigators to obtain training appropriate for the areas in which they will work by: (1) developing in-country professionals, and (2) providing opportunities to enable trained investigators returning to their home countries to serve as training resources for others.
- Enhance training to develop clinical capability and to facilitate technology transfer, including the delivery of ART; provide opportunities for foreign researchers to visit U.S. programs that serve as both models of quality care and sites for clinical studies.
- Provide training to ensure that clinicians and other health care workers understand infection control principles and can implement proper procedures in resource-poor settings.
- Ensure training that specifically includes the requirements of GCP.
- Provide training and technical assistance in the preparation of grant proposals and management of grants, including reporting requirements.
- Provide training in manuscript writing.
- Implement mechanisms to overcome language barriers so that investigators in non-English-speaking countries can have more open access to NIH grants.
- Expand training to address research administration, fiscal accountability, research support services, and grants management.
- Provide training in the ethical conduct of research, including informed consent and other topics related to the protection of human subjects.
- Encourage U.S. researchers to participate in developing country research at the research site to more fully understand the challenges of conducting research and providing care and services in such settings.

- Develop and provide training for IRBs at international sites.
- Develop and provide training at international sites conducting vaccine studies on the role and responsibilities of an institutional biosafety committee (IBC).

Collaboration and Coordination

- Enhance coordination of NIH international research efforts.
- Coordinate NIH AIDS and non-AIDS research efforts, particularly where projects are active in the same country and/or region.
- Encourage the continued development of collaborations between international and U.S. investigators, ensuring that research projects are relevant to strategic planning at the local level, to maximize the research effort in resource-limited settings.
- Enhance collaboration by providing competitive travel funds for attendance by foreign investigators at important scientific conferences to learn about the latest scientific findings and meet potential collaborators.
- Support mechanisms, such as “reentry grants,” to fund research activities of trained foreign investigators returning to their countries.
- Ensure the leadership role of in-country investigators and policy-level individuals in countries where studies take place by involving them in all stages of the research, including conceptualization of the research question, study design, development of protocols, study implementation and collection of data, data analysis, publication and presentation of research results, and interaction with the media.
- Provide assistance to foreign collaborators in addressing regulatory issues and special oversight mechanisms.
- Work with other U.S. Government agencies, including the Centers for Disease Control and Prevention (CDC), the U.S. Agency for International Development (USAID), and the State Department.
- Work with foreign governments, international organizations (e.g., WHO, with particular emphasis on coordinating research with WHO’s 3x5 Program), the Global Fund for AIDS, TB, and Malaria (GFATM), NGOs, and industry to facilitate development and testing of vaccines, microbicides, drugs, and other prevention, care, and treatment strategies, including behavioral interventions.

- Work with other U.S. Government agencies, foreign governments, international organizations, NGOs, and industry to make effective interventions resulting from research available to study participants and host-country populations.
- Explore collaboration with indigenous health providers to facilitate accomplishment of research objectives, including enhancing the participation of indigenous populations in research and improving understanding of the complexities of addressing diseases in diverse geographical settings.
- Support nurse-initiated research projects in countries with limited resources where clinical trials are already sponsored to complement and enrich their research program.
- Develop programs that foster understanding of science, the role of research, and attendant ethical issues in order to enhance reporting of AIDS issues relative to geographical areas heavily affected by the pandemic by: (1) strengthening the skills of in-country and U.S. scientists in communicating effectively to the media, and (2) educating the media to report on health research issues.
- Train policymakers in using research to affect policy.
- Expand NIH resources and expertise needed to manage and conduct international research.
- Involve experienced international researchers (both U.S. and host country) in development of international research programs, including soliciting advice on appropriate funding and administrative mechanisms, based on an understanding of challenges and constraints in diverse social, cultural, and resource-poor settings.
- Initiate a formal dialogue among NIH program staff, regulatory organizations, and experienced international researchers (both U.S. and host country) regarding the appropriate application(s), in international settings, of U.S. regulatory requirements, with the goals of optimizing ethics (including informed consent), science, and prevention in settings that differ from those of the United States.

Ethical Issues

- Ensure that research projects are designed to benefit the countries in which the research is being conducted.

- Enhance the capability of foreign institutions to conduct independent scientific and ethical reviews.
- Ensure education/cross-fertilization between developing country ethical review committees and U.S. IRBs, and educate IRBs about cultural issues in developing countries.
- Ensure the participation of local communities, NGOs, and governments in the development of research protocols.
- Ensure that ethical challenges in both research and the implementation of research results in resource-limited settings are clearly described and addressed in grant proposals.
- Consider the need for study participants and their communities in host countries to have maximum possible access to any preventive or therapeutic products developed during the research, and initiate dialogue with pharmaceutical companies early in the clinical trials planning process in resource-limited settings.
- Ensure confidentiality of information about HIV-infected individuals, including information on individuals in treatment for substance abuse.
- Include a certain percentage of individuals as members of AIDS study sections who know the importance of cultural factors and/or those who have worked in developing countries.
- Consider allowing local models of human subjects review in foreign countries to be accepted as equivalent to U.S. standards.
- Ensure that ethical review mechanisms, such as consent forms, are relevant to the country where the research is conducted and are placed in cultural context.
- Conduct workshops on ethical principles and their implementation in research, encouraging countries to develop their own set of ethical guidelines and procedures, to include the principles of respect for persons, beneficence, and justice, and the application of informed consent, assessment of risks and benefits, and selection of subjects.
- Conduct training in ethical issues and how to address them in grant applications.

- Encourage in-country scientists and leaders to work closely with local journalists to foster understanding of science, the role of research, and attendant ethical issues.
- Conduct research designed to identify ways to improve the application of ethical principles in the conduct of research in varied cultural settings, including a focus on informed consent.
- Fund studies on new models for IRB review.

Technology Transfer

- Provide improved access to information through enhanced information technology.
- Transfer clinical, laboratory, and public health technologies that may be sustained and used for implementation of prevention, symptom management, clinical training, and patient care programs once research studies are completed.

Funding Mechanisms

- Develop innovative approaches and mechanisms to provide funding for infrastructure development and for rapidly launching clinical trials, including improvement of space for confidential counseling, clinical care, and laboratory investigations (e.g., clinical research centers).
- Design flexible and rapid mechanisms to permit conduct of expanded prevention clinical trials when preliminary studies indicate that a product or approach merits full-scale evaluation.
- Continue to explore new funding approaches for international research, including direct funding of overseas investigators and provision of indirect costs to foreign institutions.
- Continue to address indirect cost issues.

OBJECTIVE - B:

Establish the most effective, affordable, practical, and sustainable approaches to care for HIV-infected adults, adolescents, and children in resource-limited settings, including:

- **Diagnosis and treatment of HIV and related conditions, such as TB, HCV, other endemic coinfections, human papillomavirus (HPV), malignancies, other STDs, neurological conditions, and nutritional deficiencies; and**
- **Critical aspects of HIV/AIDS long-term management, such as the emergence of resistance to ART and its effects at the individual and population level.**

STRATEGIES:

Treatment of HIV with Sustainable ART

- Determine affordable, safe, and effective ART regimens, including timing of initiation and appropriate drugs, that can be used in specific populations (e.g., adults, children, and adolescents) in diverse resource-poor geographic settings.
- Determine cost-effectiveness of ARVs in developing countries.
- Determine the pharmacokinetics of ARVs in various populations, including children.
- Determine the minimal necessary level of ARV resistance monitoring and the methods to be used for such monitoring.
- Determine the public health impact of ART, specifically the likelihood of transmission of resistant virus and the natural history of disease in people infected with a drug-resistant HIV strain.
- Investigate the impact of coinfections with other endemic diseases on the use of ART.
- Study drug-drug interactions among ARVs, medications for other endemic diseases, malignancies, and neurological and substance abuse therapies; traditional medicines; and medications or substances used for nonmedical reasons, as well as interactions with vaccines in standard use.

- Investigate interactions between HIV therapeutics, alcohol, drugs of abuse, or medications used for the treatment of substance abuse in pregnant women; evaluate the impact of such interactions on the maintenance of antiaddiction therapy and on MTCT.
- Study the impact of the use of nevirapine for preventing MTCT on response to ARVs in women who subsequently receive nonnucleoside reverse transcriptase inhibitor-containing HAART regimens.
- Support the long-term followup of children exposed to ART *in utero* and/or postpartum to evaluate possible late effects of exposure.
- Study treatment efficacy, side effects, and toxicity of ARVs in pediatric populations.
- Study drug compliance in children, especially as they move into and through adolescence.
- Assess the impact of nutritional status and nutritional interventions on patient survival and the efficacy and tolerability of ART.
- Study the impact of nutritional supplementation on the rate of immune system deterioration in HIV-infected persons in relation to ART.
- Determine the efficacy of ART regimens on various clades prevalent around the world.
- Conduct community-based studies that assess the impact of community mobilization on treatment success.
- Examine the potential use of HIV vaccines in the context of suppressive ART.
- Study the impact of HIV vaccines on HIV disease progression in relation to initiation of ART.
- Develop and evaluate suitable, sustainable approaches for monitoring treatment efficacy, side effects, and toxicity, with particular emphasis on finding affordable technologies to measure CD4+ cell counts and HIV load, as well as suitable alternatives.
- Determine the impact of ART on development of drug-resistant strains of HIV in diverse geographical settings, and develop strategies to limit its development.

- Develop and test appropriate measures and study levels of and barriers to adherence to HIV medications.
- Develop and test strategies to support adherence to medication to enhance therapeutic outcomes and to limit the development of drug resistance.
- Examine the effectiveness of a variety of approaches to the administration of therapy (e.g., directly observed therapy or directly delivered therapy).
- Assess the impact of ART on HIV transmission and prevalence, including associated behavior change, in various communities.
- Determine the social, psychological, societal, and economic impact of ART on individuals (including children), families, and communities, including the impact on personal risk behavior.
- Identify conditions that emerge as a consequence of ART and longer survival, such as malignancies, neurological and neuropsychological conditions, and metabolic and nutritional dysfunction.
- Determine whether expanded ARV care and treatment lead to a decrease in HIV-associated stigma and discrimination.
- Develop strategies to ensure that prevention efforts in resource-limited countries are simultaneously preserved and enhanced when clinical trial, and later ART treatment, programs are established.

Sustainable Strategies for Preventing and Treating Endemic Coinfections and Other HIV-Related Conditions

- Define the spectrum, incidence, and risk factors for HIV-related illnesses (e.g., coinfections such as TB and HCV, HPV, malignancies, and neurological conditions) in adult, adolescent, and pediatric populations specific to individual regions in diverse geographic settings.
- Study the variability in the natural history of HCV infection among different genotypes and the different rates of coinfection with HIV.
- Develop simple and cost-effective diagnostic tests for endemic coinfections and other conditions, such as TB and HCV.

- Investigate sustainable strategies for preventing, treating, and monitoring response to treatment of endemic coinfections and other HIV-related conditions.
- Assess the impact of available antibiotic treatment and prophylaxis regimens to optimize therapeutic approaches for TB and other endemic coinfections, including new therapies for TB and new approaches to administering drugs.
- Determine the safest and most efficient treatment modalities for endemic coinfections (e.g., TB, HCV, leishmaniasis, dengue fever, and malaria) in the pediatric/adolescent populations.
- Study drug-drug interactions among drugs used to prevent and treat endemic infections.
- Develop simple clinical algorithms for guiding initiation of prevention or treatment of infections.
- Identify affordable means to target high-risk patients for initiation of prophylaxis.
- Develop methods to monitor development of antimicrobial resistance by HIV-related and endemic pathogens infecting both study participants and the general population.
- Develop strategies to enhance and monitor adherence to therapy/prophylaxis for endemic coinfections.
- Determine the safety and effectiveness of available immunizations in diverse HIV-infected populations.
- Assess the burden of TB and the relative importance of reactivation versus *de novo* infection in various settings.
- Conduct studies to better understand the role and mechanism of reinfection and/or superinfection with HCV.
- Study neuropsychiatric problems in specific HIV-infected populations (e.g., women, children, and adolescents).
- Study STDs and other gynecological problems in HIV-infected women and girls.
- Study ophthalmological problems in HIV-infected children.

Approaches to Care

- Determine barriers and facilitators to acceptance of HIV testing and treatment and/or prevention recommendations.
- Develop culturally appropriate mechanisms to identify persons for whom treatment is indicated, and to overcome factors such as stigma and discrimination, which can forestall testing and limit the provision of treatment and care.
- Continue to identify better, low-cost alternatives for diagnosis of HIV.
- Develop better approaches to voluntary counseling and testing that encourage knowledge of one's status and help mitigate social harm, including changing community norms about acceptance of persons living with AIDS.
- Identify clinical management approaches, including effective palliative care strategies, and overall care needs among HIV-infected persons in diverse settings.
- Develop and evaluate care models, such as family models of care, and enhance interdependent care services that integrate AIDS care into existing programs, such as TB control programs, alcohol and other substance abuse/dependence treatment programs, and maternal and child health services, to avoid duplication of efforts.
- Develop and evaluate strategies to initiate and provide care to targeted groups of individuals, such as health care workers, security forces, and teachers.
- Develop TB prevention and education strategies for use with HIV-infected individuals, as well as the general population.

Crosscutting Strategies

- Characterize the treated history of HIV infection in diverse geographic settings.
- Examine the role of coinfections with other endemic diseases in modulating HIV, including risk of acquiring or transmitting infection and disease progression.
- Assess the impact of treatment for HIV infection on the natural history of HCV infection and the impact of treatment for HCV infection on the natural history of HIV infection.

- Work with clinicians from resource-poor settings to recruit and retain acute and early HIV infection cases in care and research programs.
- Evaluate techniques for detection of acute HIV infection, and study the effect of early identification of potential HIV transmitters on HIV infection spread in different settings.
- Support operations research to facilitate the translation of research findings to clinical practice and public health programs and to provide information to inform the scale-up of programs.

	<p>OBJECTIVE - C:</p> <p>Develop, adapt, and evaluate comprehensive biomedical, behavioral, social, and structural HIV prevention interventions appropriate for use in diverse cultural and geographical settings.</p>
STRATEGIES:	<p>Blood-Borne Transmission</p> <ul style="list-style-type: none"> • Evaluate the risk of transmission of HIV and other blood-borne pathogens through contaminated blood and medical accidents, including iatrogenic transmission. • Evaluate the effect of measures to prevent blood-borne HIV transmission, including iatrogenic transmission. • Develop strategies to prevent blood-borne transmission of HIV and HCV in health care settings, including recruitment and retention of appropriate blood donors, predonation counseling of all blood donors, improvement of blood screening strategies and technologies, and appropriate use of transfusion. • Encourage research on the relationship between the use of paid and/or professional blood donors and the dynamics of the spread of HIV infection. • Encourage research on the role of plasma and the spread of HIV infection. • Develop strategies to improve implementation of universal precautions. • Develop strategies to prevent blood-borne transmission of HIV and HCV through inappropriate or unsafe use of injections in and outside the health care setting. <p>Sexual Transmission</p> <ul style="list-style-type: none"> • Establish the most effective and sustainable ways to change or prevent high-risk sexual behaviors and practices (e.g., multiple partners, rape, trafficking of women and children into forced sex work and commercial sex work, and substance use and abuse) that foster the spread of HIV and STDs.

- Study the direct effects of ART on HIV transmission, e.g., by evaluating the effectiveness of specific ART strategies in curtailing transmission of HIV in HIV-discordant couples.
- Develop interventions targeted to both HIV-positive and HIV-negative persons and that are designed to appeal to specific populations, such as women, men, adolescents, and the military.
- Develop biomedical strategies to prevent HIV transmission by high-risk sexual behaviors, including the continued development of microbicides; studies of other preventive strategies, such as barrier methods and the factors affecting their use; syndromic management of STDs; and the cost-effectiveness of such strategies.
- Investigate the effectiveness of community-based and community-level HIV prevention programs, including prevention education based on abstinence and monogamous relationships and strategies to evaluate, replicate, and extend effective behavioral interventions.
- Develop and test prevention interventions to be used in the family context to prevent risky behavior and HIV acquisition and transmission by its members.
- Perform research into the culturally appropriate content, form, and format of instruments that will improve the quality of culturally appropriate self-reports of sexual risk behaviors.
- Improve clinical management of viral STIs, emphasizing coinfections with herpes simplex virus (HSV)-2 and HPV.
- Study gender-related biological factors affecting susceptibility to infection, including the use of hormonal contraceptives and the presence of gender-specific conditions, such as HPV infection and cervical cancer.
- Examine the role of coinfection with other endemic diseases in modulating HIV, including risk of acquiring and/or transmitting infection and disease progression.
- Study the impact of ART on preventive behaviors.
- Study the role of sexual transmission of HCV in coinfection with HIV.

Substance Use

- Investigate the role of alcohol and other commonly used psychoactive substances in promoting or facilitating sexual risk behaviors and as intervening factors that act as barriers to prevention, to reduce the efficacy of prevention strategies, and to enhance other risks for HIV, such as STDs.
- Investigate the impact of alcohol abuse, drug abuse, and other associated comorbid conditions on HIV disease progression, adherence to treatment regimens, and clinical outcomes.
- Devise strategies to prevent initiation of drug use, alcohol dependence, and transition to riskier drug practices, such as initiating drug injection and sharing of injection equipment.
- Conduct studies to identify sustainable interventions at the levels of the individual, social network, community, and society to prevent HIV and HCV transmission as a result of high-risk sexual activity and/or drug use practices associated with alcohol and drug use.
- Evaluate innovative, culturally relevant, contextually appropriate alcohol and drug abuse treatment programs for their utility as HIV and HCV prevention approaches in different international settings.
- Determine the factors involved in the injecting and noninjecting drug user's and heavy drinker's social networks that influence the rate and patterns of diffusion of HIV infection, and design prevention programs based on the results.
- Study how alcohol use, including systems of payment using alcohol, affect increases in HIV risk in seasonal and nonseasonal migrant populations.
- Conduct comparative epidemiological studies of substance use and risk for HIV and HCV in settings of varying cultural conditions and HIV seroprevalence.
- Evaluate the effectiveness of expanded access to needle and syringe exchange programs.
- Develop approaches for drug and alcohol abuse programs among HIV- and HCV- infected patients to improve adherence with drug/alcohol treatment strategies.

MTCT: Considerations for the Mother, Infant, and Child

- Develop safe, effective, feasible, and conveniently administered strategies to interrupt MTCT, using interventions that are affordable and can be implemented in resource-poor nations, including specific strategies to prevent postnatal transmission of HIV through breast milk by providing prophylaxis to the infant, mother, or both during the lactation period.
- Develop and evaluate strategies for reducing the risk of MTCT, providing safe ART to pregnant women, and assessing the effects of variable length combination ART to HIV-infected women on both MTCT and the women's own health, including the impact on subsequent pregnancies.
- Study the effect of ARV regimens used for maternal health indications on the risk of MTCT (including postnatal transmission through breast milk) and other outcomes, including pregnancy outcomes.
- Investigate the mechanisms and timing of MTCT (*in utero*, intrapartum, and postpartum via breast milk) to facilitate and develop targeted drugs/strategies to further decrease MTCT or provide alternatives to currently identified strategies.
- Further identify cost-effective, nondrug regimens for preventing MTCT, such as research on infant feeding, including:
 - ▶ acceptability of safe breastfeeding alternatives;
 - ▶ impact of the use of breast milk alternatives on morbidity and mortality of both the mother and infant;
 - ▶ breastfeeding and interaction with continued ART; and
 - ▶ role of exclusive breastfeeding.
- Conduct studies to evaluate and reduce short- and long-term toxicity of ARV drugs in women during pregnancy and in their offspring who were perinatally exposed.
- Investigate the unique immune status and develop immune interventions in both pregnant women and infants to interrupt HIV transmission.

- Examine the role of maternal and infant nutrition during the peripartum and postpartum periods in reducing morbidity and mortality in HIV-infected mothers and their infants and in reducing MTCT.
- Study the impact of the health status of HIV-infected mothers on the survivability of both HIV-infected and HIV-noninfected children.
- Study the impact of breastfeeding on the health status of HIV-infected mothers.
- Devise strategies to develop or use existing infrastructures to identify women at risk of HIV infection, and to implement treatment of them.
- Develop interventions to mitigate the negative social consequences of HIV infection, including AIDS stigma and discrimination, with particular emphasis on children infected with or affected by HIV (AIDS orphans).

Vaccine Development

- Continue the accelerated efforts toward development of vaccine candidates suitable for use around the world, and foster the development of vaccines to optimize characteristics appropriate for broad international use, including designs exhibiting low cost with ease of production and administration, as well as stability.
- Define immune approaches that will provide specific and sustained protection against HIV transmission; develop the products necessary to achieve these goals; and develop the capacity to evaluate their safety in human subjects.
- Provide a scientific knowledge base (incidence, viral subtypes, major histocompatibility [MHC] types, natural history) to justify clinical trials in international sites and to conduct trials in these sites and communities according to the highest clinical and ethical standards.
- Identify suitable populations of adults and children in which to evaluate candidate vaccines.
- Conduct Phase I, Phase II, and Phase III trials for safety, immunogenicity, and efficacy with suitable candidate vaccines in domestic and international settings.

- Enlist participation of local representatives in the development of appropriate trial protocols as well as responsive mechanisms to inform and educate the participating individuals; establish networks within the community that will effectively address the social and medical concerns of the participants; and establish mechanisms to provide ongoing information and open discussions concerning the scientific rationale of the study.
- Examine relevant behavioral issues related to the conduct of vaccines research and acceptability in diverse populations.
- Conduct research on the social and economic impact of vaccines and their cost-effectiveness.

Crosscutting Strategies

- Develop sustainable behavioral and environment-specific interventions to address multiple risk factors.
- Conduct multidisciplinary prevention research in multiple settings, including medical treatment and community support and care organizations, enhanced by rapid assessments of at-risk groups identified in each local geographic context.
- Conduct research to integrate the multiple components of diverse issues of sexuality, alcohol and other substance use, and mental health into HIV prevention programs.
- Encourage research on mechanisms to integrate prevention and care services and on the impact of integration and the organization of health services at the public health level, including evaluation, dissemination, and expansion of model programs.
- Develop new approaches to voluntary counseling and testing and assess them for cost-effectiveness and impact on reducing risk from sexual behavior and drug use in settings with varying levels of HIV seroprevalence.
- Study gender-related social and behavioral factors affecting acquisition of infection.
- Evaluate strategies to reduce stigma and discrimination and increase willingness of individuals to enter into voluntary counseling and testing; identify, accept, and undertake alternative infant feeding practices; and receive ART.

- Develop biomarkers that can serve as surrogates for measurement of HIV risk behavior and can be used to predict and monitor rapid escalation of HIV epidemics.
- Identify biological determinants of infectiousness and susceptibility to infection, including both viral and host factors.
- Study gender-related biological factors affecting susceptibility to infection, including the use of hormonal contraceptives and the presence of gender-specific conditions such as HPV infection and cervical cancer.
- Utilize population-based studies to examine basic scientific questions about HIV, mechanisms of transmission, and host response, including viral evolution, viral diversity, human immunology, and mucosal factors in transmission.
- Conduct research on how best to deliver prevention education in the care setting.
- Support operational research to facilitate the translation of research findings to clinical practice and public health programs and to provide information to inform the scale-up of programs.
- Develop links with other agencies and organizations to integrate research with service programs and to develop multidisciplinary collaboration.
- Study the psychological impact of HIV infection in women, including their role as heads of households and/or caregivers, the impact of additional pregnancies, and family support.

OBJECTIVE - D:

Conduct operational research to enhance the translation of research results into achievable and sustainable HIV prevention and treatment programs. Use advanced analytical techniques in operational research as applied to observational studies, outcome studies, cost-effectiveness studies, and epidemic modeling.

STRATEGIES:

- Conduct translational and operational research to accomplish widespread delivery of interventions to prevent transmission of HIV infection and to provide care and treatment for those individuals and families affected by HIV (e.g., ART; HIV vaccines; microbicides; treatment and prophylaxis of endemic coinfections; behavioral and other interventions, such as syndromic management of STDs and breastfeeding practices, including logistical issues on how to scale up from research projects; and drug and alcohol abuse treatment).
- Investigate the relative benefits of various approaches to provision of care and treatment.
- Develop strategies for integrating the delivery of HIV care with drug treatment, alcohol treatment, TB treatment, and other medical and social services commonly needed by HIV-infected people.
- Conduct studies, including clinical trials, on quality of care.
- Conduct research on how to scale up from pilot projects and/or early Phase I and II trials to large research populations, including Phase III trials.
- Conduct studies on effectiveness as well as efficacy.
- Conduct research on how to scale up from research studies to implementation of programs, including addressing the tension between fidelity and flexibility in scaling up.
- Integrate operational and health services research with clinical research to facilitate the translation of research findings into clinical practice and public health programs, addressing HIV in the context of other diseases, access to health care, and prevention programs.
- Conduct research on sex and gender differences in access and use of prevention and care services.

- Identify models for sustainability, and integrate research with sustainable treatment and care by coordinating U.S. research efforts with efforts of other governments, CDC, WHO, USAID, NGOs, and recipients of funding from the GFATM.
- Develop models for communication among agencies.
- Ensure the integration of U.S. research programs with established country programs, including collaboration with local investigators on strategic planning.
- Involve developing country partners, including policymakers, ministries of health, academic medical institutions, local investigators, and community advisory board (CAB) members in the development and prioritization of research agendas pertinent to their setting.
- Develop a forum for developing country partners, including policymakers, ministries of health, academic medical institutions, local investigators, and CAB members, to discuss and identify potential areas of research needed in the development and design of clinical trials and the subsequent implementation of research results in programs and policies.
- Strengthen CABs to participate in the development and design of clinical trials and other research, as well as in the translation of research results into programs and policies.
- Devise approaches to educate policymakers about research findings that are appropriate to their settings.
- Develop distance learning approaches to enhance communication of research results and translation into prevention, treatment, and care programs.
- Provide improved access to information concerning treatment and prevention guidelines and the results of research through enhanced information technology.
- Develop and provide access to guidelines for implementation of research results.
- Develop regional approaches to research (e.g., through regional meetings) to enhance communication and to address common problems and needs among countries in the region.

- Facilitate development of HIV prevention and treatment guidelines, adding behavioral, basic, and epidemiological aspects to clinical findings.

FY 2006 OAR
Planning Group for
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FY 2006 INTERNATIONAL RESEARCH PLANNING GROUP

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